STEPHEN F. HENRY, ESQ.
STATE BAR # 142336
2625 Alcatraz Avenue, # 615
Berkeley, California 94705
Telephone: (510) 898-1883
Facsimile (510) 295-2516
shenry@SHenrylaw.com

MARK L. MOSLEY (State Bar # 134349)
MOSCONE EMBLIDGE & QUADRA, LLP
220 Montgomery Street. Suite 2100
San Francisco, CA 94104
Telephone: (415) 592-4342
Facsimile: (415) 362-2006
mmosley@meqlaw.com

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

FOR THE NORTHER DISTRICT OF CALIFORNIA

MYRICK TANTIADO, an individual, Plaintiff, vs. POWER MEDICAL INTERVENTIONS, a Pennsylvania corporation, and DOES ONE through FIFTY, inclusive, Defendants.	Case No. C 07-02874 CRB MED REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF PLAINTIFF'S OPPOSITION TO MOTION FOR SUMMARY ADJUDICATION Original filing date: April 6, 2007 Removal date: June 1, 2007

Pursuant to Federal Rules of Evidence 201, Plaintiff requests this Court to take judicial notice of the attached documents.

August 15, 2008

/s/Stephen F. Henry
STEPHEN F. HENRY
Attorney for Plaintiff

EXHIBIT A

510(k) Premarket Notification Database

Device Classification Name	Staple, Implantable
510(k) Number	K032701
Device Name	SURGASSIST CIRCULAR STAPLER DIGITAL LOADING UNITS
Applicant	POWER MEDICAL INTERVENTIONS, INC. 110 Union Square Dr. New Hope Pa, PA 18938
Contact	Barbara J Whitman
Regulation Number	878.4750
Classification Product Code	GDW
Date Received	09/02/2003
Decision Date	09/30/2003
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Special
Reviewed By Third Party	No
Expedited Review	No

Database Updated 08/06/2008

SEP 3 0 2003

 K032701 (P. 1 of 5)

Special 510(k)
CORRECTIVE ACTION BEING EFFECTED
SAFETY AND EFFECTIVENESS SUMMARY

SurgASSIST *Circular Stapler Digital Loading Units®*

In Accordance with 21 CFR section 807.92 Power Medical Interventions, Inc., is submitting the following safety and effectiveness summary.

1) Submitter Information:

Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938
267-775-8151 Ph
267-775-8123 Fax

Applicant: Barbara J. Whitman

Date of Notification: August 29, 2003

2) Name of Device:

Trade Name: SurgASSIST™
Circular Stapler DLUs
21 mm, 25 mm, 29 mm, 33 mm

Common Name: Circular Stapler with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

A. SurgASSIST™ System with Circular Stapler Digital Loading Units®, (21 mm, 25 mm, 29 mm, 33 mm), with Titanium Implantable Staple, Power Medical Interventions, Inc., New Hope, PA. REF CS21, CS25, CS29, CS33 (K003277).

B. Endopath ILS Endoscopic Circular Staplers, 21 mm, 25 mm, 29 mm, 33 mm, Ethicon Endo-Surgery, Cincinnati, OH. (K920752).

4) Device Description:

The SurgASSIST™ System with Circular Stapler Digital Loading Units® (DLUs) offers computer mediated steering and stapling. The DLUs contain implantable, titanium staples and integral cutting blades. The DLUs are used to anastomose tubular structures by applying a double staggered circular row of staples through the tissue. The staples form to controlled closed conditions to secure the layers of tissue together. The DLUs also cut away the excess tissue at a controlled diameter inside the ring of staples. The Circular Stapler DLUs are available in the following four sizes: 21 mm, 25 mm, 29 mm, and 33 mm. The DLU is supplied sterilized and ready for use upon removal from its packaging.

5) Device Modification

Modifications were made to the predicate SurgASSIST™ Circular Stapler Digital Loading Units® (originally cleared under K003277) to address the root cause of the voluntary recall, which was a potential for latching mechanism failure, which could result in staple line failure and/or anvil jam. In order to further minimize the already low risk of latching mechanism failure, the spline tube and trocar were modified to improve engagement of the latch fingers. Further details of this modification can be found in Section H of this submission, under the "Device Modification" heading.

6) Indications For Use

The SurgASSIST™ Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

7) Comparison to Predicate Devices

The following table compares the subject Circular Stapler to the previously cleared predicates, Circular Stapler Cutter Digital Loading Units® (K003277) and Endopath ILS Endoscopic Circular Staplers (K920752).

Circular Stapler DLU Product Features Comparison Chart

Features & Description	**SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs)** 21 mm, 25 mm, 29 mm, 33 mm REF: CS21, CS25, CS29, CS33	**Predicate** **SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs)** 21 mm, 25 mm, 29 mm, 33 mm	**Predicate** **Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler** 21 mm, 25 mm, 29 mm, 33 mm
Name	Circular Stapler Digital Loading Units® 21 mm, 25 mm, 29 mm, 33 mm	Circular Stapler Digital Loading Units® 21 mm, 25 mm, 29 mm, 33 mm	Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler 21 mm, 25 mm, 29 mm, 33 mm
Manufacturer of Record	Power Medical Interventions, Inc.	Power Medical Interventions, Inc.	Ethicon Endo-Surgery, Inc
Contract Manufacturer	Lacey Manufacturing Bridgeport, CT	Lacey Manufacturing Bridgeport, CT	Ethicon Endo-Surgery, Inc
510(k) Clearance Numbers	Subject of this Notification	K003277	K920752
Intended use	Applications throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.	Applications throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.	Applications throughout the alimentary tract for end-to-end, end-to-side and side-to-side anastomoses.
Contraindications	Same, refer to labeling	Same, refer to labeling	Same, refer to labeling
FDA Class (System)	II	II	II
Sizes	21 mm, 25 mm, 29 mm, 33 mm Circular Staplers	21 mm, 25 mm, 29 mm, 33 mm Circular Staplers	21 mm, 25 mm, 29 mm, 33 mm Circular Staplers
Staple Shape	B-Shaped	B-Shaped	B-Shaped

K920752 (p. 3 of 5)

Case 3:07-cv-02874-CRB Document 37 Filed 08/15/2008 Page 6 of 25

Case 3:07-cv-02874-CRB Document 37 Filed 08/15/2008 Page 7 of 25

000017

Circular Stapler DLU Product Features Comparison Chart

(continued from previous page)

Features & Description	SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs) 21 mm, 25 mm, 29 mm, 33 mm REF: CS21, CS25, CS29, CS33	Predicate SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs) 21 mm, 25 mm, 29 mm, 33 mm	Predicate Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler 21 mm, 25 mm, 29 mm, 33 mm
Closed Staple Height	Approximately 1.5 mm – 2.3 mm	Approximately 1.5 mm – 2.3 mm	1.0 mm – 2.5 mm
Staple Material	ASTM F-67 Unalloyed Titanium	ASTM F-67 Unalloyed Titanium	ASTM F-67 Unalloyed Titanium
Knife Material	Stainless steel	Stainless steel	Stainless steel
DLU Materials	Polymeric materials, surgical grade stainless steels, adhesives, and lubricants	Polymeric materials, surgical grade stainless steels, adhesives, and lubricants	Polymeric materials, surgical grade stainless steels, adhesives, and lubricants
Cutting Mechanism	Circular Knife	Circular Knife	Circular Knife
DLU Internal Power	None	None	None
Power	Electrically powered via a remote Power Console	Electrically powered via a remote Power Console	Manually powered
Software containing	Yes	Yes	No
Digital Information	Memory module containing digital data for identification, etc.	Memory module containing digital data for identification, etc.	None
How Supplied	Sterile - Single Patient Use	Sterile - Single Patient Use	Sterile – Single Patient Use

K032701 (p. 4 of 5)

Circular Stapler DLU Product Features Comparison Chart

(continued from previous page)

Features & Description	SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs) 21 mm, 25 mm, 29 mm, 33 mm REF: CS21, CS25, CS29, CS33	Predicate SurgASSIST™ Circular Stapler Digital Loading Units® (DLUs) 21 mm, 25 mm, 29 mm, 33 mm	Predicate Ethicon Endo-Surgery, Inc. Endopath ILS Endoscopic Circular Stapler 21 mm, 25 mm, 29 mm, 33 mm
Safety Mechanism	Will not deploy until within an appropriate range for desired closed staple height	Will not deploy until within an appropriate range for desired closed staple height	Contains indicators for appropriate range for desired closed staple height, but can be deployed out of range
Insertion Mechanism	Flexible, steerable	Flexible, steerable	Rigid
Method of Sterilization	Ethylene Oxide Gas (ETO)	Ethylene Oxide Gas (ETO)	Irradiation
Packaging	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid	Blister Tray with Tyvek Lid

K032791 (2 of 5)

Case 3:07-cv-02874-CRB Document 37 Filed 08/15/2008 Page 8 of 25

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 0 2003

Ms. Barbara J. Whitman
Regulatory Affairs Manager
Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, Pennsylvania 18938

Re: K032701
Trade/Device Name: SurgASSIST™ Circular Stapler Digital Loading Units®
21mm, 25mm, 29mm, 33mm
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: August 29, 2003
Received: September 2, 2003

Dear Ms. Whitman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) No. K Φ32791

Device Name: *SurgASSIST™*
Circular Stapler
Digital Loading Units®
21 mm, 25 mm, 29 mm, 33 mm

INDICATIONS FOR USE:

The SurgASSIST™ Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use X OR Over-The-Counter Use _____
Per 21CFR §801.109

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032701

EXHIBIT B

510(k) Premarket Notification Database

Device Classification Name	Staple, Implantable
510(k) Number	K040024
Device Name	SURGASSIST CIRCULAR STAPLER DIGITAL LOADING UNITS
Applicant	POWER MEDICAL INTERVENTIONS, INC. 110 Union Square Dr. New Hope Pa, PA 18938
Contact	Barbara J Whitman
Regulation Number	878.4750
Classification Product Code	GDW
Date Received	01/07/2004
Decision Date	02/04/2004
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Special
Reviewed By Third Party	No
Expedited Review	No

Database Updated 08/06/2008

K040024 (p.1 of 2)

Section E
Special 510(k) – Corrective Action Being Effected
Summary

In Accordance with 21 CFR section 807.92 Power Medical Interventions, Inc., is submitting the following 510(k) Summary:

1) Submitter Information:

Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, PA 18938
267-775-8151 Ph
267-775-8123 Fax

Applicant: Barbara J. Whitman

Date of Notification: January 6, 2004

2) Name of Device:

Trade Name: SurgASSIST®
Circular Stapler DLUs – 29 mm

Common Name: Circular Stapler with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

SurgASSIST® Circular Stapler Digital Loading Units®, (21 mm, 25 mm, 29 mm, 33 mm), with Titanium Implantable Staple, Power Medical Interventions, Inc., New Hope, PA. REF CS21, CS25, CS29, CS33 (K003277 and K032701).

4) Device Description:

The SurgASSIST® Circular Stapler Digital Loading Units® (DLUs) offer computer mediated steering and stapling. The DLUs contain implantable, titanium staples and integral cutting blades. The DLUs are used to anastomose tubular structures by applying a double staggered

K040024 (P.2 of 2)

circular row of staples through the tissue. The staples form to controlled closed conditions to secure the layers of tissue together. The DLUs also cut away the excess tissue at a controlled diameter inside the ring of staples. The Circular Stapler DLUs are available in the following four sizes: 21 mm, 25 mm, 29 mm, and 33 mm. The DLU is supplied sterile and ready for use upon removal from its packaging. The purpose of this submission is to clear the modifications to the 29 mm Circular Stapler DLU only.

5) Device Modification

Modifications were made to the predicate SurgASSIST® Circular Stapler Digital Loading Units® - 29 mm (originally cleared under K003277) to address the root cause of the voluntary recall, which was a potential for latching mechanism failure. In order to minimize the risk of latching mechanism failure, addition of vent holes, heptagon design added to the trocar tip, modification to the housing, coating of the lead screws, modification of anvil stems and an addition of a latch finger spline were the design changes made to improve engagement of the latch fingers. Further details of this modification can be found in Section H of this submission, under the "Device Modification" heading.

6) Indications For Use

The SurgASSIST® Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

7) Comparison to Predicate Devices

The modified Circular Stapler Digital Loading Unit® - 29 mm maintains the same fundamental scientific technology as the predicate device. The primary change to the device is the increased strength and reliability of the latching mechanism. Details of the modifications can be found in Section H of this submission, under the "Device Modification" heading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2004

Ms. Barbara J. Whitman
Regulatory Affairs Manager
Power Medical Interventions, Inc.
110 Union Square Drive
New Hope, Pennsylvania 18938

Re: K040024
Trade/Device Name: SurgAssist® Circular Stapler Digital Loading Units® - 29 mm
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: January 6, 2004
Received: January 7, 2004

Dear Ms. Whitman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Power Medical Interventions, Inc.
SurgASSIST® Circular Stapler Digital Loading Unit® 29 mm (CS29)
Special 510(k) – Corrective Action Being Effected – January 6, 2004

Section D

Indications for Use

Power Medical Interventions, Inc.
New Hope, PA 18938

510(k) Number (if known): K040024

Device Name: SurgASSIST®
Circular Stapler Digital Loading Units® - 29 mm

Indications For Use:

The SurgASSIST® Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K040024

EXHIBIT C

510(k) Premarket Notification Database

Device Classification Name	Staple, Implantable
510(k) Number	K061649
Device Name	POWER CIRCULAR STAPLER DIGITAL LOADING UNIT WITH
Applicant	POWER MEDICAL INTERVENTIONS, INC. 2021 Cabot Blvd. Langhorne, PA 19047
Contact	Barbara J Whitman
Regulation Number	878.4750
Classification Product Code	GDW
Date Received	06/22/2006
Decision Date	09/01/2006
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Special
Reviewed By Third Party	No
Expedited Review	No

Database Updated 08/06/2008

K061649
page 1 of 2

SECTION E - Special 510(k) Summary

SEP – 1 2006

In Accordance with 21 CFR Section 807.92 Power Medical Interventions® is submitting the following safety and effectiveness summary.

1) Submitter Information:

Power Medical Interventions, Inc.
2021 Cabot Blvd.
Langhorne, PA 19047
267-775-8151 Ph
267-775-8123 Fax

Applicant: Barbara J. Whitman

Date of Notification: June 8, 2006

2) Name of Device:

Trade Name: Power Circular Stapler Digital Loading Unit®

Common Name: Circular Staplers with Implantable Staples

Classification Name: Staple, Implantable, GDW

3) Predicate Devices:

SurgASSIST® Circular Stapler Digital Loading Units®, Power Medical Interventions, Inc., K003277.

4) Device Description

Power Circular Stapler Digital Loading Units® are single use, disposable, surgical stapling devices designed for creating a circular anastomosis between two tubular structures and/or tissue layers.

5) Device Modification

The Power Circular Stapler Digital Loading Units® cut and staple identically to the predicate device, Circular Stapler Digital Loading Units® (K003277). The rigid length of the Power Circular Stapler Digital Loading Units® have been reduced by relocating portions of the gearing into the proximal end of the device, while redesigning the anvil clamping mechanism. There are Power

K061649

Page 3 of 2

Circular Staplers which incorporate a retractable dilator that is attached to the distal end of the DLU. The dilator provides a tapered leading edge, which eases DLU insertion.

6) Indications For Use

The Power Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

7) Comparison to Predicate Devices

The Power Circular Stapler Digital Loading Units® have the same indications for use and the same functionality as the previously cleared predicate Circular Stapler Digital Loading Units® (K003277). Both the Power Circular Stapler Digital Loading Units® and the Circular Stapler Digital Loading Units® deliver two staggered rows of titanium staples on each side of a circular transection. For further details, please see the Predicate Comparison Chart in Section J of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 1 2006

Power Medical Interventions
% Ms. Barbara J. Whitman
Regulatory Affairs Manager
2021 Cabot Boulevard West
Langhorne, Pennsylvania 19047

Re: K061649
Trade/Device Name: Power Circular Stapler Digital Loading Units®
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: August 7, 2006
Received: August 8, 2006

Dear Ms. Whitman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This

letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For P.J.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061649

Device Name: Power Circular Stapler Digital Loading Units®

Indications for Use:

The Power Circular Stapler Digital Loading Units® have applications throughout the alimentary tract for end-to-end, end-to-side, and side-to-side anastomoses.

Note: The Indications For Use for the Power Circular Stapler Digital Loading Units® are identical to that of the predicate device, Circular Stapler Digital Loading Units®, which were cleared to market via K003277.

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061649